



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,488	04/20/2004	Douglas A. Lorenz	PC25825A	4855
28880	7590	04/03/2008	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 GROTON, CT 06340			COPPINS, JANET L	
			ART UNIT	PAPER NUMBER
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			04/03/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,488	<b>Applicant(s)</b> LORENZ ET AL.	
	<b>Examiner</b> JANET L. COPPINS	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10-14 is/are rejected.
- 7) ☒ Claim(s) 4-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/17/04, 1/31/05, 5/23/05</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-18 are now pending in the instant application.

#### ***Information Disclosure Statement***

2. Applicants' Information Disclosure Statements (IDS), filed June 17, 2004, January 31, 2005, and May 23, 2005, have been considered by the Examiner. Please refer to the signed copies of Applicants' PTO-1449 forms, submitted herewith.

#### ***Response to Amendment***

3. Applicants' Amendment and Response, submitted January 28, 2008, has been reviewed by the Examiner. Accordingly, claims 19-22 have been cancelled.
4. The Examiner notes with appreciation the election of Group I, drawn to a process of forming amorphous atorvastatin.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10-14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- (a) Claim 10 is indefinite for reciting, "...contains a drug" at the end of the claim.

The claim language is vague because it is unclear from the claim itself what is meant by the term "drug," i.e. if Applicants are intending to claim another (different) compound, or the prodrug form of the compound, or an additional active ingredient, etc. Clarification is requested. The

Art Unit: 1626

Examiner also cautions Applicants when amending the claim that they must be enabled for whatever "drug" they are intending to recite.

(b) Claim 11 is indefinite for reciting "...a mean average diameter of less than 500 m." The scope of the claim is confusing since the range encompassed by "less than 500" includes any diameter from 0-499 m.

(c) Claim 12 is indefinite for reciting "...a mean average diameter of less than 100 m." The scope of the claim is confusing since the range encompassed by "less than 100" includes any diameter from 0-99 m.

(d) Claim 13 is indefinite for reciting "...a span of about 3 or less." The scope of the claim is confusing since the range encompassed by "3 or less" includes any span from 0-3.

(e) Claim 14 is indefinite for reciting "...a span of about 2.5 or less." The scope of the claim is confusing since the range encompassed by "2.5 or less" includes any diameter from 0-2.5.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/42209 A1, to Pflaum, Zlatko. Applicants are claiming a process of forming amorphous atorvastatin, comprising the steps of: dissolving atorvastatin in a hydroxylic solvent, and then rapidly evaporating the solvent to form amorphous atorvastatin.

The WO document teaches a process of producing amorphous atorvastatin, wherein a crystalline form of atorvastatin is dissolved in a low molecular alcohol (i.e. a hydroxylic solvent) and then the solution is dried by evaporation.

Regarding the “second solvent” present in the solutions of the WO document, Applicants recite that atorvastatin is dissolved in a solution “**comprising** a hydroxylic solvent”. Regarding the term “comprising,” the Examiner directs Applicants’ attention to Chapter 2100 of the MPEP, please see 2111.03 [R-3], under Transitional phrases:

The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) (“like the term comprising,” the terms containing’ and mixture’ are open-ended.”). < *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) (“The transition comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.”); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”). > In *Gillette Co. v. Energizer Holdings Inc.*, 405

Therefore, as claimed, the solution is open-ended and may contain additional solvents, as discussed in the WO document.

Regarding claims 2 and 3, please refer specifically to pages 9 and 10, in which several Examples are taught wherein atorvastatin is dissolved in methanol or ethanol and then the solution is evaporated away. The Examiner recommends incorporating some of the latter claims into claims 1-3, in order to distinguish the instant claims from the prior art processes.

***Claim Objections***

10. Claims 4-18 are objected to as being depending on rejected base claims.

***Conclusion***

11. In conclusion, claims 1-18 are pending, claims 1-3 and 10-14 are rejected, and claims 4-18 are also objected to.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. COPPINS whose telephone number is (571)272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins  
March 27, 2008

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626  
Kamal A. Saeed,  
Primary Examiner, Art Unit 1626